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9. 510(K) SUMMARY

Submitted By:

Margaret J. Posner, Regulatory Affairs Specialist
Wilson-Cook Medical Inc.
4900 Bethania Station Road
Winston-Salem, NC 27105-4191
336-744-0157
July 29, 2002

Names of Device:

Trade Name:	Wilson-Cook Cystotome
Common/Usual Name:	Endoscopic electrosurgery device
Classification Name:	Endoscopic electrosurgery accessory 21 CFR 876.4300 (78KNS); Class II

Predicate Devices:

The Wilson-Cook Cystotome is comparable to predicate devices including the Wilson-Cook Needle Knife Papillotome (K972674); the Boston Scientific Autotome™ RX (K013153); and the Boston Scientific Microvasive Gold Probe (K970278).

Device Description:

The Wilson-Cook Cystotome consists of an inner wire with needle knife tip, a 5 Fr inner sheath, and a 10 Fr outer sheath equipped with a diathermic ring at its distal tip. The proximal end of the device will include a handle with connectors for active cords and a fitting to provide for injection of contrast fluid.

Intended Use:

The Wilson-Cook Cystotome is intended for use as an electrosurgical accessory to electrosurgically cannulate the transgastric or transduodenal wall and into a pancreatic pseudocyst, when it is visibly bulging into the gastrointestinal tract. It is supplied sterile and is intended for single use.

Substantial Equivalence:

The Wilson-Cook Cystotome is comparable to predicate devices with similar technological characteristics and intended use, specifically to perform electrosurgical procedures through an endoscope.

Discussion of Tests and Test Results:

The Wilson-Cook Cystotome underwent electrical testing, simulated use testing, and clinical testing. Test results provide reasonable assurance the device will perform in accordance with its intended use.

Conclusions Drawn from Tests:

Being similar to predicate devices with respect to intended use and technology, and having test results that indicate the device will perform in accordance with its intended use, the Wilson-Cook Cystotome meets the requirements for 510(k) substantial equivalence.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 17 2002

Ms. Margaret J. Posner
Regulatory Affairs Specialist
Wilson-Cook Medical
GI Endoscopy
4900 Bethania Station Road
WINSTON-SALEM NC 27105

Re: K022595
Trade/Device Name: Wilson-Cook Cystotome
Regulation Number: 21 CFR 876.4300
Regulation Name: Endoscopic electrosurgical unit and accessories
Regulatory Class: II
Product Code: 78 KNS
Dated: August 2, 2002
Received: August 5, 2002

Dear Ms. Posner:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

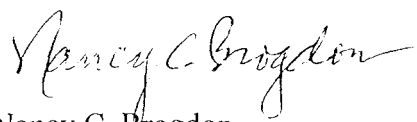
This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,



Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K022595

Device Name: Wilson-Cook Cystotome

Indications For Use:

The Wilson-Cook Cystotome is intended for use as an electrosurgical accessory to cannulate the transgastric or transduodenal wall and into a pancreatic pseudocyst that is visibly bulging into the gastrointestinal tract. This device is supplied sterile and is intended for single use only.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Donna A. Seymour

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K022595

✓ Prescription Use ____ OR Over-The-Counter Use
(Per 21 CFR 801.109) (Optional Format 1-2-96)